NIH258.001DV1 PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Patent Number 7,201,911 Group Art Unit: 1633

Name of Patentee : Yanagi et al.

Title

CLONED GENOMES OF

INFECTIOUS HEPATITIS C

VIRUSES AND USES THEREOF

Issued April 10, 2007

> REQUEST TO "MAKE OF RECORD" NOTED ERRORS

Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

Dear Sir:

Errors by the Patent and Trademark Office have been noted in the recently issued aboveidentified Letters Patent as follows:

SEE ATTACHED

Since these are inconsequential errors, a Certificate of Correction is not needed, but it is requested that this Letter be made of record by being included in the patent file.

Please charge any fees to Deposit Account No. 11-1410.

Respectfully submitted,

KNOBBE, MARTENS, OLSON & BEAR, LLP

Dated: October 31, 2007

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Bv:

Knobbe Martens Olson & Bear

Issued Patent Proofing Form

File #: NIH258.001DV1

Proofread By: Alka (08/07/2007) US Serial No.: 09/662,454

US Patent No.: US 7,201,911 B1 Issue Date: Apr. 10, 2007 Title: CLONED GENOMES OF INFECTIOUS HEPATITIS C VIRUSES AND USES THEREOF

Sr.	Original		Issued Patent		Description of Errors
No.	Page	Line	Column	Line	
1	Page 1 Issue Fee Payment (PTO-85B) (03/02/2007)	1 (Name of Assignee)	First Page Col. 1 (Assignee)	1	Before "United States" insert The Government of the
2	Page 1 of 1 List of references cited by examiner (04/09/2002)	Entry 2 Line 2 (Non-Patent Documents)	First Page Col. 2 (Other Publications)	4	Delete "Cofirmation," and insert Confirmation,, therefor.
3	Page 1 of 1 List of references cited by examiner (01/27/2006)	Entry 1 Line 1 (Non-Patent Documents)	First Page Col. 2 (Other Publications)	6	Delete "chilenge" and insert challenge, therefor.
4	Sheet 1 of 4 List of References cited by applicant and considered by examiner (04/09/2002)	Entry 2 Line 2 (Other Documents)	First Page Col. 2 (Other Publications)	16	Delete "pp/" and insert pp, therefor.
5	Sheet 2 of 4 List of References cited by applicant and considered by examiner (04/09/2002)	Entry 1 Line 2 (Other Documents)	First Page Col. 2 (Other Publications)	24	Delete "transfedted" and insert transfected, therefor.
6	Sheet 2 of 4 List of References cited by applicant and considered by examiner (04/09/2002)	Entry 2 Line 3 (Other Documents)	First Page Col. 2 (Other Publications)	30	After "vol." delete "69 ," and insert 69, -, therefor. (Consider Space)
7	Sheet 2 of 4 List of References cited by applicant and considered by examiner (04/09/2002)	Entry 3 Line 2 (Other Documents)	First Page Col. 2 (Other Publications)	33	Delete "thehypervariable" and insert the hypervariable, therefor. (Consider Space)
8	Sheet 3 of 4 List of References cited by applicant and considered by examiner (04/09/2002)	Entry 1 Line 2 (Other Documents)	First Page Col. 2 (Other Publications)	42	After "No. 6" insert ,

9	Sheet 3 of 4 List of References cited by applicant and considered by	Entry 3 Line 1 (Other Documents)	First Page Col. 2 (Other Publications)	46	Delete "Heptatis" and insert Hepatitis, therefor.
	examiner (04/09/2002)	,			
10	Sheet 3 of 4 List of References cited by applicant and considered by examiner (04/09/2002)	Entry 4 Line 1 (Other Documents)	Page 2 Col. 1 (Other Publications)	1	Delete ""Structure" and insert "Structural, therefor.
11	Sheet 4 of 4 List of References cited by applicant and considered by examiner (04/09/2002)	Entry 1 Line 1 (Other Documents)	Page 2 Col. 1 (Other Publications)	4	Delete "Enymatic" and insert Enzymatic, therefor.
12	Sheet 4 of 4 List of References cited by applicant and considered by examiner (04/09/2002)	Entry l Line 1 (Other Documents)	Page 2 Col. 1 (Other Publications)	4	Delete "Activites" and insert Activities, therefor.
13	Sheet 1 of 2 List of References cited by applicant and considered by examiner (12/05/2006)	Entry 3 Line 1 (Non Patent Literature Documents)	Page 2 Col. 1 (Other Publications)	21	After "Houghton" delete "M." and insert M,, therefor.
14	Sheet 1 of 2 List of References cited by applicant and considered by examiner (12/05/2006)	Entry 4 Line 1 (Non Patent Literature Documents)	Page 2 Col. 1 (Other Publications)	25	After "Puig" delete "M." and insert M,, therefor.
15	Sheet 1 of 2 List of References cited by applicant and considered by examiner (12/05/2006)	Entry 6 Line 3 (Non Patent Literature Documents)	Page 2 Col. 2 (Other Publications)	1	Delete "gentic" and insert genetic, therefor.
16	Sheet 2 of 2 List of References cited by applicant and considered by examiner (12/05/2006)	Entry 2 Line 2 (Non Patent Literature Documents)	Page 2 Col. 2 (Other Publications)	22	Delete "persistance," and insert persistence,, therefor.

17	Sheet 2 of 2 List of References cited by applicant and considered by examiner (12/05/2006)	Entry 4 Line 1 (Non Patent Literature Documents)	Page 2 Col. 2 (Other Publications)	27	Delete "Braky" and insert Brasky, therefor.
18	Page 7 Drawings (09/14/2000)	18 (FIG. 4D)	Sheet 7 of 49 (FIG. 4D)	18	Below "6400" delete "6900" and insert 6450, therefor.
19	Page 7 Drawings (09/14/2000)	19 (FIG. 4D)	Sheet 7 of 49 (FIG. 4D)	19	Above "6550" delete "6950" and insert 6500, therefor.
20	Page 13 Drawings (09/14/2000)	2 (Below Figure) (FIG. 6)	Sheet 13 of 49 (FIG. 6)	2 (Below Figure)	Delete "(infextious" and insert (infectious, therefor.
21	Page 1 Specification (09/14/2000)	6	1	8	After "1997" insert
22	Page 7 Specification (09/14/2000)	33	4	43	Delete "pHSO $_1$)." and insert pH50 $_1$), therefor.
24	Page 9 Specification (09/14/2000)	6	5	21	After "nucleotide" insert sequence
24	Page 9 Specification (09/14/2000)	9	5	23	After "amino acid" insert sequence
25	Page 9–10 Specification (09/14/2000)	36 and 1	5	(Approx.)	Delete "Cons-p 9." and insert Cons-p9, therefor. (Consider Space)
26	Page 10 Specification (09/14/2000)	20	6	2	After "study)" insert
27	Page 10 Specification (09/14/2000)	21	6	3	Delete "HVR 1" and insert HVR1, therefor. (Consider Space)
28	Page 1 Miscellaneous Incoming Letter (09/14/2000)	14 (Preliminary Amendment)	6	3	Before "SEQ ID" insert (
29	Page 1 Miscellaneous Incoming Letter (09/14/2000)	15 (Preliminary Amendment)	6	4	After "45" insert)
30	Page 1 Miscellaneous Incoming Letter (09/14/2000)	15 (Preliminary Amendment)	6	4	Before "SEQ" insert (
31	Page 1 Miscellaneous Incoming Letter (09/14/2000)	16 (Preliminary Amendment)	6	5	After "46" insert)

32	Page 10 Specification (09/14/2000)	32	6	15	Before "pCV-H77C)" insert (
33	Page 11 Specification (09/14/2000)	5–6	6	31	Delete "pCv-J4L6S" and insert pCV-J4L6S, therefor.
34	Page 11 Specification (09/14/2000)	20	6	47	Before "FIGS." insert and
35	Page 11 Specification (09/14/2000)	21	6	47	After "amino acid" insert sequence
36	Page 11 Specification (09/14/2000)	31	6	57	After "1a/1b" insert clone
37	Page 11 Specification (09/14/2000)	34	6	60	Delete "pCV-H77C," and insert pCV-H77C, therefor.
38	Page 2 Miscellaneous Incoming Letter (09/14/2000)	(Preliminary Amendment)	6	66	Delete "NO:65)," and insert NO:65), therefor.
39	Page 17 Specification (09/14/2000)	23	9	62	Delete "pCv." and insert pCV, therefor.
40	Page 27 Specification (09/14/2000)	30	15	8 (Approx.)	Delete "calorimetric" and insert colorimetric, therefor.
41	Page 30 Specification (09/14/2000)	3	17	22 (Approx.)	Delete "Ti" and insert T1, therefor.
42	Page 30 Specification (09/14/2000)	31–32	17	51 (Approx.)	Delete "PGEM-9zf(-)" and insert pGEM-9zf(-), therefor.
43	Page 31 Specification (09/14/2000)	9	17	65	Delete "6° C." and insert 68° C, therefor.
44	Page 32 Specification (09/14/2000)	15	18	53 (Approx.)	Delete "H77Consensus" and insert - H77 Consensus, therefor. (Consider Space)
45	Page 32 Specification (09/14/2000)	32	19	5	Delete "3° C." and insert 37° C, therefor.
46	Page 33 Specification (09/14/2000)	2	19	10	Delete "-8° C." and insert80° C, therefor.
47	Page 33 Specification (09/14/2000)	19	19	27 (Approx.)	Delete "(p.i)" and insert (p.i.), therefor.
48	Page 38 Specification (09/14/2000)	17	22	11	Before "other" delete "a".

49	Page 40 Specification (09/14/2000)	3	23	3	Delete "-8° C." and insert80° C, therefor.
50	Page 40 Specification (09/14/2000)	12	23	(Approx.)	Delete "H3X58R" and insert H3'X58R, therefor.
51	Page 41 Specification (09/14/2000)	5–6	23	41	Delete "(5'AGGATGGC" and insert (5'-AGGATGGC, therefor.
52	Page 3 Miscellaneous Incoming Letter (09/14/2000)	7 (Preliminary Amendment)	23	42	After "-3")" insert SEQ ID
53	Page 41 Specification (09/14/2000)	11	23	47	Delete "6° C." and insert 67° C, therefor.
54	Page 46 Specification (09/14/2000)	25	26	39 (Approx.)	Delete "(0.34k)" and insert (0.34%), therefor.
55	Page 51 Specification (09/14/2000)	26	26	29 (Approx.)	Delete "DCV-H77C" and insert pCV-H77C, therefor.
56	Page 54 Specification (09/14/2000)	2	30	43 (Approx.)	Delete "Hepatolocy" and insert Hepatology, therefor.
57	Page 54 Specification (09/14/2000)	5	30	45 (Approx.)	Delete "Helatolocy" and insert Hepatology, therefor.
58	Page 55 Specification (09/14/2000)	16	31	19	Delete "Hepatolocy" and insert Hepatology, therefor.
59	Page 56 Specification (09/14/2000)	5	32	8 (Approx.)	Delete "Virolocy" and insert Virology, therefor.

* * * OBSERVATIONS * * *

In the Reference Files, List of references cited by examiner (04/09/2002), Page 1 of 1, Entry 1, under "Non-Patent Documents" and List of References cited by applicant and considered by examiner (04/09/2002), Sheet 2 of 4, Entry 2, under "Other Documents", respectively, are given as follows:

Byoung J. Yoo et al, Transfection of a Differentiated Human Hepatoma Cell Line (Huh7) with In Vitro-Transcribed Hepatitis C Virus (HCV) RNA and Establishment of a Long-Term Culture Persistently Infected with HCV, Jan. 1995, p. 32-38, vol. 69, No. 1.

Yoo et al, "Transfection of a Differentiated Human Hepatoma Cell Line (Huh7) with In Vitro-Transcribed Hepatitis C Virus (HCV) RNA and Establishment of a Long-Term Culture Persistently Infected with HCV", Journal of Virology, vol. 69, No. 1, Jan. 1995, pp. 32-38.

The above two Entries seem to be **similar** and both the Entries have been incorporated in the **Issued Patent**.

2. In the Reference Files, List of references cited by examiner (04/09/2002), Page 1 of 1, Entry 2, under "Non-Patent Documents" and List of References cited by applicant and considered by examiner (04/09/2002), Sheet 1 of 4, Entry 3, under "Other Documents", respectively, are given as follows:

Nelson Fausto, Editor-in-Chief, Replication of Hepatitis C Virus in Tissue Culture: A Potential Breakthrough in Need of Cofirmation, vol. 151, No. 2, Aug. 1997.

Fausto, "Replication of Hepatitis C Virus in Tissue Culture: A Potential Breakthrough in Need of Confirmation", American Journal of Pathology, vol. 151, No. 2, Aug. 1997, p. 361.

The above two Entries seem to be **similar** and both the Entries have been incorporated in the **Issued Patent**.

- 3. According to Preliminary Amendment (09/14/2000), Pages 2–3, SEQ ID NO: 7, SEQ ID NO: 8, SEQ ID NO: 9, SEQ ID NO: 10, SEQ ID NO: 11, SEQ ID NO: 12, SEQ ID NO: 13, SEQ ID NO: 14, SEQ ID NO: 15 and SEQ ID NO: 17 should be inserted after "H9261F", "H93"X58F", "H9282F", "H3"X45R", "H9375F", "H3"X-35R", "H9386F", "H3"X-38R", "H1" and "H941R", respectively, in TABLE 1. However, in the Issued Patent all the insertions have been made above the corresponding numbers.
- 4. According to Preliminary Amendment (09/14/2000), Pages 2–3, SEQ ID NO: 7, SEQ ID NO: 8, SEQ ID NO: 9, SEQ ID NO: 10, SEQ ID NO: 11, SEQ ID NO: 12, SEQ ID NO: 13, SEQ ID NO: 14, SEQ ID NO: 15 and SEQ ID NO: 17 should be inserted after "H9261F", "H3'X58R", "H9282F", "H3'X45R", "H9375F", "H3'X-35R", "H9386F", "H3'X-35R", "H1" and "H941R", respectively, in TABLE 1. However, SEQ ID NO: 16 is missing which seems inappropriate and it should be incorporated after "A1" on Col. 17, Line 6 (Approx.) of Issued Patent.

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